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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/834,815 | 04/13/2001 | Barnett S. Pitzele | PHAR 7978/3312US | 8682 |

7590 10/10/2002

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[REDACTED] EXAMINER

ZUCKER, PAUL A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1621 | 8 |

DATE MAILED: 10/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/834,815 | PITZELE ET AL | |
| | Examiner | Art Unit | |
| | Paul A. Zucker | 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 July 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Current Status

1. This action is responsive to Applicants' amendment of 22 July 2002 in Paper No 7.
2. Receipt and entry of Applicants' amendment is acknowledged.
3. Claims 1-28 remain outstanding.
4. The objection to the specification set forth in paragraph 2 of the previous Office Action in Paper No 6 is withdrawn in response to Applicant's amendment.
5. The provisional rejection for double patenting set forth in paragraph 4 of the previous Office Action in Paper No 6 is maintained in view of Applicants failure to file a terminal disclaimer.

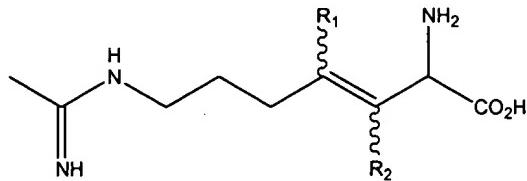
The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

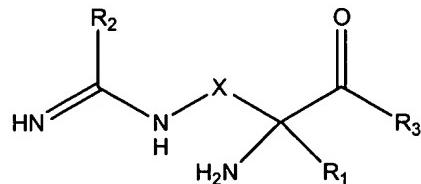
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-28 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al (WO 95/25717-A1 10-1995) and further in view of Hallinan et al (US 6,344,483 02-2002).

The invention is directed toward the compounds (geometric and stereoisomers) of Formula (I), where R₁ and R₂ may be H or methyl, or their pharmaceutically acceptable salts :



Currie generically discloses (Page 4, line 1-page 5, line 10) a genus of nitric oxide synthase inhibitors of general formula (I):



Where R₃ may be hydroxyl, R₂ may be methyl and R₁ may be hydrogen or lower alkyl (methyl). A preferred embodiment of the compounds is further taught (Page 7 line 9-21) where X= lower alkenyl, lower alkynyl, where lower denotes 1-6 carbons. Currie further teaches (Page 7, lines 27-30) alkyl substitution of the alkenyl and alkynyl core.

Hallinan teaches (Column 3, line 24 - column 4, line 48) nitric oxide synthase inhibitors closely related in structure to Currie's and refers (Column 3, line 3) to Currie's disclosure directly. Hallinan further discloses alkenyl (Column 18, line 1 –

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column 19, line 2) and alkynyl (Column 19, line 3- column 20, line 27) amidino amino acids.

Hallinan's disclosure and teachings provide the motivation for one of ordinary skill in the art to actually synthesize the alkenyl and alkynyl compounds taught by Currie.

Thus the instantly claimed compounds would have been obvious for one of ordinary skill in the art. The motivation for combination of the two references is provided by the reference by Hallinan to Currie as well as the common field of invention. The expectation for success would have been near certitude since Currie's genus completely embraces the instant compounds which, Currie teaches, have the instantly desired activity as nitric oxide synthase inhibitors.

Examiner's Response to Applicant's Arguments with Regard to This Rejection

7. Applicant has put forth several arguments with regard to this rejection. The Examiner responds below:

- a. Applicant argues that no example in Currie has a double bond in any position of the carbon chain. The Examiner agrees with this observation but points out that such is not required to render the instant invention obvious over the teaching of Currie. Currie provides clear direction toward the compounds of the instant invention in his teaching of alkenyl compounds as a preferred embodiment of his invention (Page 7 line 9-21; see rejection above).
- b. Applicant further argues that Hallinan exemplifies only halogenated compounds. Again, the Examiner agrees with Applicants' observation. The

Examiner also points out, however, that Hallinan's teaching of alkenyl functionality in the carbon chain simply reinforces Currie's clear teaching toward the instant compounds notwithstanding Hallinan's teaching of halogen substitution.

Applicant's arguments filed 22 July 2002 have been fully considered but they are not persuasive for the reasons indicated above.

Conclusion

8. Claims 1-28 are outstanding. Claims 1-28 are finally rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Paul A. Zucker
Patent Examiner
Technology Center 1600

October 6, 2002



Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600